

510(k) Summary (21 CFR § 807.92(c))

Submitter: CrossBay Medical, Inc.
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Date Summary Prepared: 18 March 14

Device Trade Name: CrossBay Medical SonoSure Sonohysterography and Endometrial Sampling Device

Common Name: Saline Infusion Sonohysterography (SIS) Catheter, Endometrial Brush

Classification Name: Obstetric-gynecologic specialized manual instrument
(21 CFR §884.4530)

Product Code: PGK (cannula, injector, uterine, endometrial biopsy)
HFE (endometrial brush)

Equivalent Devices: Cook's Sonohysterography Biopsy Device (K060908 – 29 Jun 2006)
Cook's Tao Endometrial Sampling Brush (K082066 – 07 Nov 2008)

Device Description:

The CrossBay Medical SonoSure Device is a catheter that enables saline infusion sonohysterography procedures and endometrial biopsy collection within a single device. The catheter is comprised of standard polymer materials and contains a silicone acorn tip to enable a cervical seal. The distal end of the device contains a retractable nylon brush for endometrial biopsy sampling. The distal end of the device contains an empty PVC bag that can be filled with saline. The device is provided sterile and is intended for single use only.

Intended Use / Indications for Use:

The CrossBay SonoSure Sonohysterography and Endometrial Sampling Device is indicated for use to access the uterine cavity for saline infusion sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device.

Technological Characteristics & Substantial Equivalence: The Cook® Sonohysterography Biopsy Catheter served as the primary predicate device. The subject and predicate device have the same Indications for Use statement. The subject and predicate device have different technological characteristics as follows: mechanism of endometrial biopsy collection, dimensions, and design. The predicate device incorporates a curette to perform endometrial biopsy while the subject device utilizes a brush. However, the second predicate device, the Cook® Tao Endometrial Sampling Brush, also utilizes a brush to collect endometrial biopsy samples.

The different technological characteristics of the subject device could affect safety and effectiveness. For example, regarding effectiveness, the different mechanism of endometrial biopsy collection may affect the adequacy of the sample. Regarding safety, the different mechanism of endometrial biopsy collect may affect the pain and/or discomfort associated with the procedure. The remaining different technological characteristics between the subject and predicate device are minor and should have minimal impact on safety and effectiveness.

The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions as they are routinely encountered during premarket review of uterine catheters, endometrial aspirators, and endometrial brushes.

Accepted scientific methods exist to assess the effects of the different technological characteristics, including mechanical, animal, and/or clinical performance testing. The submission included sufficient performance data to assess the effects of the different technological characteristics, and the performance data demonstrate equivalence.

Non-Clinical Performance Data: Physical bench testing confirmed that the CrossBay Medical SonoSure Device performs according to the product specifications. Device evaluation consisted of physical, chemical and functional testing performed pursuant to the device verification protocol. Mechanical safety and performance testing was conducted to ensure adherence of the endometrial biopsy brush bristles to the catheter shaft when subjected to shear force. Additionally, this bench safety evaluation included force at break assessments. Biocompatibility testing was conducted according to ISO 10993 "Biological Evaluation of Medical Devices" and FDA's recent guidance ("Use of International Standard ISO 10993", draft document issued on 24 April 2013). The following biocompatibility tests were conducted: Cytotoxicity, Sensitization and Irritation. The sterilization validation complies with the requirements prescribed in the applicable standards for ethylene oxide sterilization (ISO 11135-1:2007 "Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" and ISO 10993-7:2008 "Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals"). Packaging and shipping validation studies were conducted pursuant to the applicable ASTM guidelines (ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials"; and, ASTM F1929 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"). The results of shelf life testing demonstrate that the packaging for the subject device maintains sterility over the duration of

shelf life, the packaging can withstand transport without damage, and the subject device maintains its mechanical safety and performance over the duration of its shelf life

Summary:

Based on the product technical information, intended use / indications for use and bench performance data provided in this premarket notification, the CrossBay Medical SonoSure Device has been shown to be substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

CrossBay Medical, Inc.
% Cindy Domecus, R.A.C.
Principal
Domecus Consulting Services, LLC
17141 Murphy Avenue, Suite 5C
Irvine, CA 94901

Re: K133144
Trade/Device Name: SonoSure SonoHysteroGRAPHY and Endometrial Sampling Device
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: PGK, HFE
Dated: February 18, 2014
Received: February 19, 2014

Dear Cindy Domecus,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number if Known: K133144

Device Name: CrossBay Medical SonoSure Sonohysterography and Endometrial Sampling Device

Indications for Use:

The CrossBay SonoSure Sonohysterography and Endometrial Sampling Device is indicated for use to access the uterine cavity for saline infusion sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S

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